

CLAIMS

- 1) A pharmaceutical formulation having a masked taste,
the masking of which persists during administration of
5 the formulation, in particular, in the form of a
suspension in an aqueous vehicle, comprising:
- a) - a cellulosic polymer which is soluble in organic
solvents but practically insoluble in water,
regardless of the pH;
 - 10 - a methacrylic polymer which is soluble in an acid
medium and practically insoluble at a neutral or
alkaline pH and
 - an active ingredient distributed in a homogeneous
manner and in the molecular state in the mixture,
15 which is in the form of an atomized matrix;
 - b) a pharmaceutically acceptable alkaline agent of an
organic nature or an alkaline salt; and
 - c) an adsorbent agent.
- 20 2) The formulation according to claim 1, wherein the
cellulosic polymer and the methacrylic polymer are
respectively ethylcellulose and a cationic polymer
formed from 2-dimethylaminoethyl methacrylate and
neutral methacrylates.
- 25 3) The formulation according to claim 1 wherein the
alkaline agent and the adsorbent agent are chosen
respectively from the group consisting of meglumine,
lysine, sodium and potassium citrate and sodium and
30 potassium carbonate, and from the group consisting of
magnesium aluminum silicate and talc.
- 4) The formulation according to claim 3 wherein the
alkaline agent and the adsorbent agent are respectively
35 meglumine and magnesium aluminum silicate.
- 5) The formulation according to claim 1 wherein the

active ingredient is an antibiotic of the macrolide or macrolide-like, cephalosporin, penicillin, tetracycline or quinolone type.

- 5 **6)** The formulation according to claim 5, wherein the active ingredient is telithromycin.
- 7)** The formulation according to claim 1 wherein:
- 10 - the cellulosic polymer is present in the atomized matrix in a proportion ranging from about 30% to about 50% by weight and the methacrylic polymer is present in a proportion ranging from about 10% to about 25% by weight; and
- 15 - the active ingredient is present in the atomized matrix at a maximum level of about 50% by weight.
- 8)** The formulation according to claim 7, wherein the proportions of cellulosic and methacrylic polymers in
- 20 the matrix range respectively from about 40% to about 45% and from about 15% to about 20% by weight, and in that the maximum amount of the active ingredient in the matrix is about 30% by weight.
- 25 **9)** The formulation according to claim 1 which also comprises within the matrix a hydrophobic plasticizing agent and/or an antioxidant agent.
- 10)** The formulation according to claim 1 which further
- 30 comprises one or more elements chosen from preservative agents, sweetening agents, thickening agents and flavoring agents.
- 11)** A process for the preparation of a pharmaceutical
- 35 formulation comprising:
mixing a cellulosic polymer and a methacrylic polymer and, optionally, a hydrophobic plasticizing agent and

an antioxidant agent in an organic solvent;
adding the active ingredient to the above mixture;
passing the solution thus obtained through an atomizer
in order to obtain a product in the form of an
5 atomized matrix; and
mixing the product with an alkaline agent and an
adsorbent agent, optionally, with one or more elements
chosen from the group consisting of preservative
agents, sweetening agents, thickening agents and
10 flavoring agents.

12) The process according to claim 11 wherein the organic
solvent used is chosen from the group consisting of
halogenated hydrocarbons, alcohols and ketones.

13) The process according to claim 12 wherein the solvent
is methylene chloride.

14) The process according to claim 11 wherein the
cellulosic polymer is soluble in organic solvents but
practically insoluble in water, regardless of the pH;
and the methacrylic polymer is soluble in an acid
medium and practically insoluble at a neutral or
alkaline pH.

15) The process according to claim 14 wherein the
cellulosic polymer and the methacrylic polymer are
respectively ethylcellulose and a cationic polymer
formed from 2-dimethylaminoethyl methacrylate and
neutral methacrylates.

16) The process according to claim 11 wherein the active
ingredient is an antibiotic of the macrolide or
macrolide-like, cephalosporin, penicillin,
tetracycline or quinolone type.

17) The process according to claim 16 wherein the active ingredient is telithromycin.

5 18) The process according to claim 11 wherein the alkaline agent and the adsorbent agent are chosen respectively from the group consisting of meglumine, lysine, sodium and potassium citrate and sodium and potassium carbonate, and from the group consisting of magnesium aluminum silicate and talc.

10 19) The process according to claim 18 wherein the alkaline agent and the adsorbent agent are respectively meglumine and magnesium aluminum silicate.

15 20) The process according to claim 11 wherein:
- the cellulosic polymer is present in the atomized matrix in a proportion ranging from about 30% to about 50% by weight and the methacrylic polymer is present in a proportion ranging from about 10% to
20 about 25% by weight; and
- the active ingredient is present in the atomized matrix at a maximum level of about 50% by weight.

25 21) The process according to claim 20, wherein the proportions of cellulosic and methacrylic polymers in the matrix range respectively from about 40% to about 45% and from about 15% to about 20% by weight, and in that the maximum amount of the active ingredient in the matrix is about 30% by weight.

30 22) A process for masking the taste of a pharmaceutical product intended for oral administration in an aqueous suspension, wherein said active ingredient is entrained homogeneously inside a matrix comprising
35 combining at least a cellulosic polymer and a methacrylic polymer with at least an alkaline agent and an adsorbent agent.